

REMARKS

Interview Summary

A telephonic interview was held at Applicant's on request February 25, 2009, at 11:30 AM EST, and lasted approximately 30 minutes. Present remotely were inventors Dr. James Roberts, Janey Lau and Ralph Cowden and their undersigned counsel. Attending for the Office were Examiner Adam Milligan and Supervising Examiner Jeff Lundgren.

The inventors explained the background and significance of the invention, the unexpected synergies experienced and results obtained by those who had used the invention, and the availability of case studies illustrating these synergies and results. Rozema (J. Advancements Med. 1997), the primary reference relied upon by the Office, was also briefly discussed. Applicant indicated its intention to amend Claim 1 to address the ambiguity highlighted by the Examiner. Applicant also indicated it would consider submitting declarations documenting the case studies that supported its claim of unobviousness. No exhibits or demonstrations were shown or conducted, no other claims amendments were discussed, and no specific agreements were reached.

The Examiner's courtesy in granting Applicant an after final interview is acknowledged with appreciation.

Claim Objection

Applicant has further amended independent claim 1 by adopting the clarifying language suggested by the Examiner. Applicant appreciates the Examiner's patience on this issue.

Claims Rejections – 35 USC § 103

Applicant's Reply to The Final Office Action Dated January 7, 2010

In response to the Final Office Action, Applicant repeats and incorporates by this reference the arguments and authority submitted in its October 22, 2009 amendment and response and, in addition, respectfully points out the following:

1. Applicant disagrees with the Examiner's assertion that in Applicant's invention "the EDTA [i]s being administered [orally] to remove the heavy metals from

tooth fillings which may have progressed through the digestive track in order to chelate the heavy metals in the stomach or intestines prior to absorption of the heaving metals into the blood stream.” Final Action at 3. Applicant’s oral EDTA dosage is specifically designed and formulated for absorption into the blood stream through the small intestine. See Specification generally. Enteric coating the oral EDTA dose is described as a significant limitation in both the Specification and Claims. Enteric coating the oral dose of the subject nutritional protocol is at odds with having the EDTA available to chelate heavy metals in the stomach and small intestines.

2. The Examiner’s reliance on *Merk & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 975 (1989), is inappropriate. *Merk* stands for the proposition that the Office is entitled to rely upon non-preferred embodiments of an invention that are described by the prior art. Oral administration of EDTA cannot fairly be described as a non-preferred embodiment of Rozema. The Federal Circuit has “decline[d] to extract from *Merk [& Co. v. Biocraft Laboratories Inc.]*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that . . . regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it.” *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992); MPEP § 2144.08.

Rather, Rozema teaches that the oral administration of EDTA is not a viable avenue for EDTA chelation therapy. According to Rozema, absorption into the blood stream is very poor and orally administered (non-enteric coated) EDTA interferes with the absorption of essential minerals and trace elements in the gut. Rozema at 16. Consequently, “the most effective route of administration for most of the recurrently recognized clinical benefits appears to be intravenous. . . .” *Ibid.* Rozema teaches away from Applicant’s oral EDTA dosage form.

“A *prima facie* case of obviousness may also be rebutted by showing that the art, **in any material respect**, teaches away from the claimed invention.” MPEP § 2144.05 III (emphasis in the original), citing *In re Geisler*, 116 F.3d 1465, 1471, 432 USPQ2d 1362, 1366 (Fed. Cir. 1991).

2. The addition of vitamin C to an EDTA containing oral dosage form to promote absorption of the EDTA through the small intestine into the blood stream is not

made obvious by Rozema. Rozema notes that vitamin C may act synergistically with EDTA as an effective chelation agent. Final Action, at 4. Rozema nowhere notes that vitamin C “also enhances absorption of the ‘Defend Life’ [and] ‘Protect Life’ active agents.” Specification at 4. Because Rozema cautions against attempting to administer EDTA orally, Rozema was not aware of and would have had no reason to be concerned with vitamin C’s role in promoting the absorption of EDTA through the intestinal wall. As such Rozema neither teaches nor renders obvious combining vitamin C with EDTA in the context of an oral pharmaceutical.

3. Applicant is appending rebuttal evidence which demonstrates that the claimed invention yields unexpected properties, unexpectedly improved properties, and properties not present in the prior art. MPEP § 2145 citing *In re Dillon*, 919 F.2d 688 at 692-93, 16 USPQ2d 1897 at 1901 (Fed. Cir. 1990). “Evidence that the compound or composition possesses superior or unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness.” TMEP § 2145 citing *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). “Patentability may be imparted . . . if the results achieved at the designated concentrations are ‘unexpectedly good’” *Merk, supra*, 874 F.2d at 809, quoting *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, 42 CCPA 824 (1955).

Rozema teaches intravenous EDTA as the most effective route for administration. Applicant’s Rejuvetate Life System, wherein the EDTA is administered orally, gives “results [that are] as good if not better than those found with patients undergoing intravenous EDTA chelation therapy.” Declaration of James C. Roberts M.D., F.A.C.C., (“Roberts Declaration”) attached.

User testimonials and case evaluations performed by cardiologist Dr. Roberts supports the conclusion that the Rejuvetate Life System possesses unexpected properties, unexpectedly improved properties, and superior properties compared with the other commercially available products and compared with the properties and results that might reasonably be expected by combining the cited prior art (e.g., Rozema, Kolilainen, Rabussay, Hsia and others). See Roberts Declaration and Exhibit 2 attached thereto; Declaration of Janey Lau (“Lau Declaration”) and Exhibit A attached thereto.

“Applicant can rebut a presumption of obviousness . . . by showing ‘(1) [t]hat the prior art taught away from the claimed invention . . . or (2) that there are new and unexpected results relative to the prior art.’” MPEP § 2144.05 III, quoting *Iron Grip Barbell Co. vs. USA Sports, Inc.*, 392 F.3d 1317, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004). Here Applicant has done both.

Evidence of Secondary Considerations Rebut Any Prima Facie Showing of Obviousness and Render the Invention Considered as a Whole Unobvious

“As reiterated by the Supreme Court in *KSR* [550 U.S. 398 (2007)], the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).” MPEP § 2141 II. That framework includes the evaluation of “objective evidence relevant to the issue of obviousness. [*Graham v. John Deere Co. supra*] at 17-18, 148 USPQ at 467. Such evidence, sometimes referred to as ‘secondary considerations,’ may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results.” MPEP § 2131 II.

Secondary considerations provide an alternative mode of analysis to determine whether the invention at issue was obvious. Unlike the other inquiries laid out in *Graham*, secondary considerations do not focus on the abstract technological content of the invention and the prior art. Instead, secondary considerations look to the historical events that surrounded the marking of the invention and its introduction to the marketplace.

* * *

At their root, [secondary considerations] are circumstantial evidence from which the obviousness or non-obviousness of the invention can be inferred.

3 Moy’s Walker on Patents § 9:54 at 9-199 (4th ed. 2008).

The value of secondary considerations are that they tend to be less subjective in their application compared with the primary *Graham* factors. *Ibid.*

Appended to this after final response are declarations of three of the inventors. Taken together, there declarations demonstrate three of the four secondary considerations set forth by the *Graham* court and reaffirmed by the *KSR* court. Demonstration of only one factor can be sufficient to give rise to an inference that rebuts a *prima facie* showing of obviousness.

In April 2004, Applicant began marketing the Rejuvetate Life System, a four bottle nutritional protocol that is described in the Specification and that is encompassed in new independent claim 14. Prior to the introduction of Applicant's product, those wanting to practice EDTA chelation therapy were obligated to undergo intravenous treatments at clinics or use commercially available suppository products. Declaration of Ralph A. Cowden, III ("Cowden Declaration"), attached.

Once introduced, Applicant's product enjoyed immediate and unexpected commercial success. Sales grew 15 percent per quarter (60% per year), and Applicant captured at least 12 percent of the EDTA health supplement market, selling approximately 15,000 units and grossing in excess of \$1,000,000. Lau Declaration; Cowden Declaration.

Results obtained by those using the Rejuvetate Life System are unexpectedly good. Most users reported having more energy, none experienced strokes or kidney stones while on the regimen, and some reported improved dental checkups, improvement in diseases of the veins and diabetes. Lau Declaration. Users who underwent clinical testing while on the regimen showed consistent improvement in coronary artery disease, carotid artery blockage and blood lipid concentrations. Roberts Declaration.

Doctor James Roberts, a board certified and well credentialed cardiologist with experience in a variety of traditional and alternative treatments for individuals suffering from serious coronary artery diseases, found that patients on the Rejuvetate Life System obtained results that are as good as if not better than those undergoing intravenous EDTA chelation therapy. Roberts Declaration.

This evidence, taken together, demonstrates that Applicant's invention as embodied in the Rejuvetate Life System (1) successfully addresses a long felt but unsolved need for an effective EDTA chelation therapy that can be administered at home, orally, with minimal effort or expense; (2) gives rise to the unexpected result of addressing simultaneously and effectively a number of important health issues and, in particular, addressing serious circulatory diseases as well as, if not better than, intravenous EDTA chelation therapy; and (3) has enjoyed extraordinary commercial success since its recent launch in mid-2004.

Office personnel should evaluate the totality of the facts and all of the evidence, including evidence of secondary considerations, to determine whether, in light of the applicant's rebuttal evidence, the facts and evidence would still support a conclusion that the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. MPEP § 2144.08 II A and cases cited therein.

“[T]he question under 35 U.S.C. § 103 is not whether the differences [between the claimed invention and the prior art] would have been obvious” but “whether the claimed invention as a *whole* would have been obvious. (emphasis in original).” *Ibid.*, quoting *Stratoflex, Inc. vs. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983). Here, the “invention embraces both the individual compositions and the treatment protocol with one or more of the four stages.” *Specification*, ¶¶ 4 & 12. Taken as the whole, and applying both the primary and secondary *Graham* considerations, Applicant's invention as claimed is not obvious in view of the prior art alone or in combination.

Conclusion

Pending claims 2 through 9 and 11 through 13 include all limitations of amended independent claim 1, as does new independent claim 14. According claims 1 through 9 and 11 through 14 are unobvious in view of Rozema alone or Rozema in combination with Kotilainen.

Alternatively and in addition, inasmuch as Applicant has provided persuasive evidence that the Rejuvetate Life System as reflected in new independent claim 14 solves a long-felt but unsolved need, demonstrates unexpected synergies and results, and has met with unanticipated commercial success, claim 14 is unobvious in view of Rozema alone or in combination with Kotilainen and others.

CONCLUSION

In light of the remarks, authority and evidence argued above, the amended claims listing set forth below, and the evidence in the form of declarations with exhibits attached hereto, Applicant submits that all claims currently pending in the application, being nutritional protocol claims 1-9 and 11-14, should be allowed or, alternatively, that at least

new claim 14, reflecting the complete protocol for which compelling evidence has been provided, should be allowed. Applicant further submits that it should be given the opportunity to amend apparatus claim 10 to include all limitations of method claims 1 or 14, such that apparatus claim 10 may be rejoined with the allowed method claims in accordance with MPEP § 821.04.

This Amendment and Response is being electronically transmitted via EFS-Web this day HST (expected receipt on March 7, 2010), within two months of the three month time period allowed for response and within the time entitling Applicant to an advisory action. No extension fees are due. The amended claims (3 independent and 14 total) are within the number originally paid for.

The Examiner is invited to contact the undersigned attorney at (808) 521-7080, business hours Hawaii standard time, or via email at <seth.reiss@lex-ip.com>, in order that the undersigned attorney may endeavor to resolve any outstanding issues as expeditiously as possible thereby to avoid prolonged prosecution of this application.

Respectfully submitted,

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